DECEMBER 2001

REPORT TO THE CONGRESS

Blood Safety in Hospitals and Medicare Inpatient Payment

MEDPAC Medicare Payment Advisory Commission

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Executive summary

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Hospitals' costs for blood and blood products have increased more rapidly than overall operating costs over the past 15 years, due mostly to newly imposed safety requirements and the costs of technologies needed to meet them. In addition, blood-related costs probably increased significantly in fiscal year 2001 as a result of increases in the price of blood products. Three new safety technologies may cause future cost increases, with the impact concentrated in hospitals that transfuse large quantities of blood.

The Congress asked the Medicare Payment Advisory Commission (MedPAC) to study how much of the increase in hospital costs from fiscal year 1984 to fiscal year 1999 can be attributed to complying with new blood safety requirements and providing services using new blood safety technologies. We also were asked to examine whether the inpatient prospective payment system (PPS) has adequately recognized these costs, to estimate future cost increases in response to new safety technologies, and to consider changes in the inpatient PPS to recognize them. This report gives our response to each of these issues and presents the Commission's recommendation that the Centers for Medicare & Medicaid Services (CMS) account explicitly for the cost of blood and blood products by reintroducing a separate component for their prices when it next revises the hospital market basket.

Blood-related costs increased more rapidly than all hospital costs between 1986 and 1999. Because these costs make up less than 1 percent of overall hospital costs, however, the faster growth of blood costs increased overall Medicare hospital costs by a total of less than 0.5 percent over this period. The proportionate contribution of blood costs has been greater since 1995, and the large price increase in 2001 will have an even greater effect. Nonetheless, payment increases exceeded increases in overall and blood-related costs through FY 1999.

The collection, processing, and distribution of blood and blood products has changed greatly since 2000. After the emergence of AIDS in the early 1980s and the spread of infection through transfusions, both the federal government and the blood banking industry sought means to help ensure blood safety through new regulations, voluntary standards, professional practices, and improved technology.

Voluntary standards, private accreditation rules, and Food and Drug Administration regulations address safety issues at blood banks. They deal with procedures for screening and deferring donors, testing and quarantining blood, and correcting system deficiencies. New technologies likely to play an important role in ensuring safety and increase costs in the future include nucleic acid amplification testing, leukoreduction, and pathogen inactivation.

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 required CMS to give special attention to the adequacy of payment for blood and blood products when revising the market basket. MedPAC recommends that CMS modify the market basket to better reflect changes in the price of blood and blood products. CMS could reintroduce a separate cost component for blood using the producer price index for blood and derivatives as price proxy. Through fiscal year 1996, the agency market basket used this approach. CMS dropped the separate component for blood when it revised the hospital market basket for FY 1997, citing the lack of appropriate data for calculating a weight for blood services. The agency should explore using alternative data sources to develop a weight when it next revises the hospital market basket. ■

Blood Safety in Hospitals and Medicare Inpatient Payment

RECOMMENDATION

When CMS next revises the hospital market basket, it should explicitly account for the cost of blood and blood products by reintroducing a separate component for their prices.

*** YES: 14 • NO: 0 • NOT VOTING: 0• ABSENT: 3**

***COMMISSIONERS' VOTING RESULTS**

Blood-related costs have increased more rapidly than overall operating costs in hospitals over the past 15 years, raising the question of whether these costs are accounted for appropriately in Medicare's payments to hospitals.

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) required the Medicare Payment Advisory Commission (MedPAC) to study the increase in hospital costs over FYs 1984 to 1999 that was associated with new blood safety requirements and with providing services using new blood safety technologies. The BIPA required that we examine whether the inpatient prospective payment system (PPS) has adequately recognized these increased costs. It also required us to estimate cost increases in response to new safety technologies over the next 10 years and to consider changes in the inpatient PPS to recognize future cost increases.

This report begins with a review of available measures of price for blood products and presents an analysis of changes in blood prices from 1984 to 1999. The discussion of prices is followed by results of MedPAC's analysis of changes in Medicare inpatient blood-related costs in hospitals from 1986 to 1999. Next we present an overview of features of Medicare's inpatient PPS relevant to treatment of blood-related costs, followed by an overview of safety regulations, standards, and technology. The report concludes with a recommendation on how costs for blood and blood products should be handled in the payment system. An appendix presents detailed information on blood safety regulations and technologies, based on research by MedPAC and by Project HOPE under contract.

Trends in blood prices and costs

MedPAC's analysis of hospital-level cost data and Medicare patient bills shows that blood-related costs increased more rapidly than all costs in PPS hospitals between 1986 and 1999.[1] Because blood-related costs comprise less than 1 percent of overall hospital costs, however, faster growing blood costs increased overall costs by a total of less than 0.5 percent over this period. The proportionate contribution of blood costs has been greater since 1995, and a large price increase in 2001 will have an even greater effect. Nonetheless, the cost of blood has limited impact on overall hospital costs.

Trends in prices

Blood and blood components are sold on local markets in which a small number of blood centers offers a variety of products for purchase by local hospitals or for shipment to other areas to assist local blood centers in meeting demand. The American Red Cross, by far the largest supplier of blood and blood products, establishes a national price policy and then adapts prices to local markets.

The most inclusive measure of prices for blood and blood products is the producer price index (PPI) for blood and derivatives (see text box, page 6), which reflects prices for serums, plasma, and blood derivatives for human use. It includes several products derived from plasma that are not typically used by hospital transfusion services. The prices for the PPI are obtained through a regular data collection system.

[1] We examined data for 1986 because available patient bill information on blood charges are incomplete in 1984 and unreliable in 1985. Reporting of these charges was exceedingly poor during this period of the changeover to the inpatient PPS.

The structure of the blood banking industry

In 1999, approximately 13.9 million units of whole blood were collected at domestic blood centers and hospitals transfused 12.4 million units of whole blood and red blood cells (National Blood Data Resource Center 2001).[2] Half of all transfusions are received by Medicare beneficiaries (Muse and Associates 2000).

Blood and blood components are generally obtained by donation from unpaid volunteer donors. Virtually all blood donations are collected by the 1,800 institutional members of the American Association of Blood Banks (Lipton and Wiegmann 2000). These include all American Red Cross blood collection centers and most independent community blood banks, hospital-based blood banks, and hospital transfusion services. In 1999, hospitals collected 7 percent of donated whole blood (National Blood Data Resource Center 2001). The rest was divided between community blood centers and the centralized Red Cross system.

The Red Cross accounts for about half of all blood collected in the United States and receives $1.5 billion annually from hospitals and other organizations for collecting, testing, and distributing blood and tissue products (American Red Cross 2000). It operates a national organization of facilities that test, process, and supply hospitals with blood and provides blood to approximately 3,000 hospitals (American Red Cross 2001). It is organized into four areas with a total of 36 regions, although its presence in some states is limited to a few markets. Regions are legally separate entities but the Red Cross operates under one Food and Drug Administration (FDA) license. Regions that experience shortages receive blood from regions that experience surpluses.

In addition to Red Cross and other blood collection centers which collect whole blood from volunteer donors, approximately 370 centers collect plasma (the liquid portion of whole blood) for use in producing plasma-derived blood products such as albumin and immune globulins (GAO 1998). These commercial enterprises generally pay donors.

About 800 hospitals collect allogeneic or autologous blood.[3] In addition, most hospitals obtain blood from Red Cross blood centers or independent community blood centers, generally by contracting with a single local blood bank to meet all their demand for blood products. If a blood bank cannot meet hospital demand due to local supply problems, the facility may seek blood from other sources, often at higher prices. One-fifth of hospitals report seeking alternative sources of supply when faced with blood shortages (AHA 2001a). ■

[2] Whole blood is blood that is collected in an anticoagulant or preservative and not further processed. Red cells are concentrated by the removal of most of the plasma from sedimented or centrifuged whole blood. (AABB 2000).

[3] Allogeneic blood is donated for use by another person, either a stranger or a specific "directed" individual (e.g., a relative of the donor). Autologous blood is collected to be later used by the same donor/recipient.

TABLE 1

Comparison of price measures: annual growth in the producer price index for blood and derivatives and prices for individual blood products

Price index	1984–1990	1990–1995	1995–1999	1984–1999	1999–2000
Blood and derivatives PPI	2.6%	0.7%	6.8%	3.0%	–6.4%
Red blood cell fees	5.5	4.7	3.9	4.8	8.2
Fresh frozen plasma	NA	3.5	1.6	NA	5.0
Platelet concentrates	NA	4.0	1.1	NA	4.0

Note: PPI (producer price index), NA (not available).

Source: MedPAC analysis of data from the Bureau of Labor Statistics and America's Blood Centers.

Prices differ among types of blood products. Whole blood/red blood cells account for approximately half of all inpatient transfusions in the United States, with various components accounting for the rest. To assess the impact on hospitals of changes in the prices of blood and associated products, we constructed more narrow price indexes for red blood cells, plasma, and platelets using information on fees reported by America's Blood Centers, the organization of independent blood centers. Data from the organization are developed from a regular survey of its members, which provide about half of the nation's blood supply. Unfortunately, we have no information on how representative the data are of prices charged by the association's members or the industry as a whole. In addition, the indexes do not include information from the Red Cross, which provides approximately half of the nation's blood supply and may follow different pricing practices.

The price data for red blood cells, plasma, and platelets cover much of the market for blood and blood products. Because each component is narrowly defined, reported fees and the indexes calculated from them will be less sensitive to changes in the mix of products sold over time than a broader index such as the PPI. Although the PPI provides a more complete picture of price changes for blood products, the indexes for red blood cells, plasma, and platelets better reflect the products used by hospitals.

The prices of blood products increased erratically between 1984 and 1999, and alternative price indexes provide inconsistent measures of price growth (Table 1). The index for red blood cells shows higher growth than the PPI for blood and derivatives from 1984 through 1995, and this pattern is reversed from 1995 through 1999. The rate of growth in the PPI increases after 1995 while price growth slows for red blood cells, plasma, and platelets. In 2000, the blood PPI dropped and the divergence between the PPI and the red blood cell index grew.

None of the data reflects the price increases instituted by the American Red Cross in July 2001, which ranged from 10 to 35 percent (AHA 2001b). In a recent survey, hospitals reported increases in prices averaging 26 percent for blood from the American Red Cross and 12.7 percent for blood purchased from community-based blood centers from 2000 to 2001 (AHA 2001c).

What is the producer price index?

The producer price index (PPI) is a family of indexes that measures changes in wholesale prices received by domestic producers for goods and services. More than 10,000 individual PPIs measure changes in prices for specific products or groups of products.

The PPI compares expenditures in a base period to current expenditures for a fixed set of goods. It is a weighted sum of current period prices for specified goods relative to prices in a base period, with each good's weight equal to its share of expenditures in a base period. PPIs based on prices for individual items or groups of items can be aggregated to calculate a higher-level index. The PPI for biological products is such an index and reflects the prices of commodities including blood, vaccines, and related products.

Collecting data

The Bureau of Labor Statistics (BLS) collects price data from a sample of establishments that agree to report information regularly. In constructing the PPI for biological products, for example, the BLS collects data from entities that produce serums, plasmas, and other blood derivatives, as well as products such as vaccines, toxoids and allergenic extracts. The BLS publishes indexes for the main commodity grouping of chemicals and allied products, a drugs and pharmaceuticals subgroup, a biological products class, and a subproduct class for blood and derivatives, human use.

Keeping indexes up to date

The BLS changes its product sample when new goods are introduced and old ones phased out. This resampling occurs more frequently in industries experiencing rapid changes in production technology or industry structure. The indexes in the biological products class are updated every six or seven years; they were most recently updated in 1993 and are scheduled for updating in the near future.

The BLS attempts to adjust for changes in product quality by comparing new and old products and incorporating data on costs of change, or by statistical analysis (hedonic regression). Such adjustments raise issues about identifying changes in quality and their costs, the cost of data collection, and the risk of introducing inaccuracy into price series.

Price indexes for medical products should account for considerations of appropriate output measurement and technological change. Producer prices of blood and blood products are affected by these factors. Although each category of blood product (for example, whole blood or plasma) is generally a well-defined and stable class, technological changes have affected the quality of blood products. Because the changes may not be fully reflected in the PPI for blood and derivatives, increases in index values may not correctly reflect increases in prices for comparable products. ■

TABLE 2

Annual change in Medicare blood-related costs per discharge—all patients, fiscal years 1986–1999

Cost measure	1986–1990	1990–1995	1995–1999	1986–1999
Overall operating cost per discharge	9.0%	2.0%	1.1%	3.8%
Blood-related cost per discharge	6.2	4.1	2.0	4.1

Note: Based on cost report data for cohorts of hospitals in fiscal years 1986, 1990, 1995, and 1999.

Source: MedPAC analysis of data from the Centers for Medicare & Medicaid Services.

Trends in blood-related costs in hospitals

To learn more about the cost of blood to hospitals, MedPAC looked at overall Medicare blood-related costs using the cost reports of hospitals covered by Medicare's acute inpatient PPS. We also estimated Medicare blood costs using case records, which allowed us to restrict the analysis to blood users (patients who received transfusions).

Hospital cost report analysis

From 1986 to 1999, blood costs per discharge increased at an annual rate of 4.1 percent, compared with a 3.8 percent increase in overall operating costs per discharge (Table 2). These averages reflect more rapid growth in operating costs before 1990 and more rapid growth in blood costs from 1990 to 1999.[4] Growth in blood cost per PPS discharge reflects changes in the cost per unit of blood, changes in the quantity of blood per user, and changes in the number of users as a share of all patients.

Hospital stay analysis

For this analysis, we used data on the hospital stays of 20 percent of Medicare patients in each fiscal year (calendar year for 1986). We combined these data with information from Medicare cost reports for the facilities in which patients were hospitalized and summed across all patients to arrive at estimates of blood-related and overall costs per discharge for patients who used blood.[5]

Blood-related costs per discharge for users grew less rapidly than overall cost per user before 1990, and more rapidly after 1990 (Table 3, page 8). Over the entire 1986 to 1999 period, blood cost per user increased at an annual rate of 4.1 percent, compared with 3.5 percent for total cost per user. This led to an increase in blood cost as a percent of total cost for the same users from 3.2 percent in 1986 to 3.4 percent in 1999.[6]

[4] Hospital reporting of these costs is inconsistent and incomplete. In the 1999 file available for the analysis, which contained data on 3,322 hospitals (approximately 60 percent of PPS hospitals), 628 hospitals reported data in the cost center for blood and 1,001 reported data in the cost center for blood administration.

[5] Blood-related costs are based on charges for blood and blood administration. Total costs include inpatient routine care, special care, and ancillary services. We used cost-to-charge ratios for blood and blood storage and processing to estimate blood-related costs from charges. We used routine cost per day, intensive care unit cost per day, cardiac care unit cost per day, and the inpatient ancillary cost-to-charge ratio applied to ancillary charges to estimate overall costs.

[6] This 3.2 - 3.4 percent share differs from the 0.6 percent share of costs for blood-related costs in the hospital market basket used before FY 1997 because it measures only the costs of blood users—about one-fifth of cases—rather than the costs of all cases.

TABLE 3

Annual change in Medicare blood-related costs per discharge for patients who use blood, 1986–1999

Cost measure	1986–1990	1990–1995	1995–1999	1986–1999
Overall operating cost per discharge	7.6%	2.4%	0.8%	3.5%
Blood-related cost per discharge	6.4	4.8	1.1	4.1

Note: Based on Medicare beneficiaries hospitalized in prospective payment system hospitals in calendar year 1986; fiscal years 1990, 1995, 1999.

Source: MedPAC analysis of data from the Centers for Medicare & Medicaid Services.

PPS payment context and policy options

Medicare's inpatient PPS pays hospitals a fixed amount per discharge for an all-inclusive bundle of services provided by the hospital. The payment reflects the estimated costs of all inputs used to treat a Medicare case and does not depend on whether blood or any other specific resource is used.[7] Hospitals have been able to offset price increases on some inputs by reducing the use of other inputs and by shifting the latter days of many patient stays to post-acute settings such as skilled nursing facilities, rehabilitation centers, and home care. As a result, payment increases under Medicare's acute inpatient PPS have exceeded hospitals' cost increases every year from 1992 through 1997. Provisions of the Balanced Budget Act of 1997 (BBA) resulted in reduced payment growth since then, but the cumulative increase in payments has still been considerably greater than the increase in hospitals' costs from 1992 through 1999 (MedPAC 2001). Payments per discharge under Medicare's inpatient PPS increased at a rate of 4.3 percent—more than the growth in either blood costs or overall costs—from 1986 through 1999.

CMS annually modifies the weights for diagnosis related groups (DRGs) to reflect changes in the relative costliness of different types of cases. It calculates weights using data on hospital charges, which are available with a two-year lag. Changes in charges in fiscal year 2001, including those due to increases in prices for blood products, will modify the DRG weights and relative payments for fiscal year 2003.

Hospital payment updates are determined principally by the rate of increase in the hospital market basket, but CMS and MedPAC consider other factors affecting increases in cost when making their recommendations for annual updates to PPS payment rates. The Congress considers these recommendations, as well as other information, in legislating the final update.

[7] Medicare inpatient hospital payment rules require a deductible for blood. The beneficiary must pay for the first three units of blood used during a calendar year. Since not-for-profit blood centers generally do not charge for blood and blood products, under Medicare rules beneficiaries may not be charged for units that would otherwise be subject to the deductible. Providers may charge for the testing, storage, and distribution services provided by blood centers. These charges are not subject to the blood deductible. Additional payments are made for blood clotting factor furnished to a Medicare inpatient who is a hemophiliac.

The hospital market basket

The PPS Hospital Input Price Index, the market basket used for PPS inpatient hospital operating costs, is intended to measure the change in prices of a fixed basket of goods and services that hospitals use to provide patient care. The market basket increase indicates the expected rise in hospital operating costs, given no changes in the resources used to provide patient care and the types of patients treated. Each market basket cost component is assigned a weight, which reflects its share of hospital operating expenses nationally in a base year, and a price proxy, which estimates the change in the unit prices for the component. The price measures for all but one component (liability insurance) are from the BLS. Twelve of the price proxies used in the market basket are producer price indexes published by the BLS.

CMS uses a forecast of the market basket to set payment updates subject to existing statute. The overall forecast is made up of forecasts of the component price indexes, multiplied by their weights and then aggregated.

The agency periodically revises the market basket components and weights to keep them representative of hospital purchases and to accommodate the changing availability of data. CMS conducted its most recent revision in 1997 to update payment rates for fiscal year 1998. It is likely to revise the market basket's weights again in 2002 to reflect the current allocation of costs among cost components in time to update rates for fiscal year 2003. As part of that process, CMS will evaluate the appropriateness of the current set of market basket components and the indexes used to measure price changes.

Updating PPS payments

The Congress has legislated the PPS update annually since fiscal year 1986 and has generally stated the update in relation to the forecasted change in the market basket. The Congress considers information from numerous sources in setting the update, including MedPAC, CMS, and stakeholders. Payment updates have been set by the BIPA as the change in the market basket minus 0.55 percent for fiscal years 2002 and 2003, and equal to change in the market basket thereafter in the absence of additional Congressional action.

Treatment of blood in Medicare payment policy

Before 1997, the hospital market basket included a separate component for blood services adjusted by the PPI for blood and derivatives. As part of its regular rebasing of the market basket, CMS combined components to form a new category that included blood-related costs, and began adjusting it by the PPI for industrial chemicals. This PPI is unrelated to blood prices both conceptually and in underlying data.

The PPI for "blood & derivatives, human use," used in the market basket before 1997, is part of the family of indexes for chemicals and allied products. Within this larger family, it is part of a subgroup of indexes for biological products (Table 4, page10). This subgroup includes indexes for vaccines, toxoids, diagnostics, and other biological products for human use, as well as other items for veterinary and industrial use.[8] The PPI for industrial chemicals is also part of the family for chemicals and allied products. However, it includes a set of products that does not overlap with those included in biological products.

[8] Products for human use account for 93 percent of the price change of the biologicals products index (BLS 2001).

TABLE 4 **Structure of producer price indexes for chemicals and allied products**

Chemicals and allied products

Industrial chemicals
- basic inorganic chemicals
- basic organic chemicals

Drugs and pharmaceuticals
- over-the-counter drugs
- prescription drugs
- medicinal and botanical chemicals
- veterinary preparations
- biological products
  - blood and derivatives, human use
  - vaccines, toxoids, and antigens for human use
  - diagnostics and other biologicals
  - biologicals for veterinary use
  - biological products for industrial and other use

Source: Bureau of Labor Statistics.

The BLS publishes measures of relative importance that show relationships among price indexes. Biological products were 0.311 percent of all commodities included in the overall PPI in December 2000; its subindex, "blood & derivatives, human use," was 0.033 percent. (For comparison, prescription drugs, as reflected by the PPI for "Preparations, ethical [prescription]," were 1.221 percent [BLS 2001]). Blood prices contribute a modest amount to the change in the PPI for biological products.

We examined the historical growth rates of the price indexes for blood and derivatives and industrial chemicals. We also looked at an alternative index that could be used in the market basket for blood costs. For comparison, we use the growth in the hospital market basket as a standard.

The PPI for blood and derivatives increased slightly less rapidly than the market basket between 1984 and 1999, with much slower rates in the early 1990s and faster rates in the late 1990s (Table 5). A 6.4 percent decrease in the blood and derivatives PPI in 2000 yields 4.0 percent growth for 1995-2000 and 2.4 percent growth over the 1984-2000 period. The PPI for industrial chemicals has consistently increased more slowly than the hospital market basket, and between 1995 and 1999—when blood prices grew rapidly—it actually decreased. The PPI for biological products grew at about the same rate as the index for blood and derivatives from 1984 to 1999, with faster growth before 1995 and slower growth from 1995 through 1999.

Safety regulation, standards, and technology

The collection, processing, and distribution of blood and blood products has changed greatly since 1984. After the emergence of AIDS in the early 1980s and the spread of infection through transfusions, the federal government and the blood banking industry sought means to help ensure safety through new regulations, voluntary standards, improved practices, and enhanced technology. These changes, as well as local shortages of blood during the 1990s, appear to have contributed to price increases.

TABLE 5

Annual change in selected producer price indexes and the hospital market basket

Index	1984–1989	1989–1995	1995–1999	1984–1999
Hospital market basket	4.3%	3.5%	2.4%	3.5%
Blood and derivatives	3.1	0.6	6.8	3.0
Industrial chemicals	3.5	1.9	–1.9	1.4
Biological products	4.3	2.1	2.3	2.9

Source: MedPAC analysis of data from the Centers for Medicare & Medicaid Services and the Bureau of Labor Statistics.

Private standards and accreditation rules address safety issues at blood banks. In addition, the FDA regulates all aspects of blood bank operations including safety. Table 6 (page 12) presents a time line of regulatory and technological changes that have occurred since 1983. (Appendix A, page 17, provides more detail on regulation, standards, and technology relating to blood safety.) These events tend to fall into three categories:

- **Screening and deferring donors** A deferral occurs when a blood center declines a donor's blood. Potential donors are screened through questionnaires covering their medical histories, places they have traveled, and other issues that might indicate potential problems. Several regulatory changes over the years have been related to screening and deferral. A current example relates to Creutzfeldt-Jakob Disease (CJD) and Variant CJD (vCJD), bovine spongiform encephalopathy, the human form of "mad cow" disease. The FDA's "Guidance to Industry" on CJD recommended that donors who have lived in the U.K. for three months or more between 1980 and 1996 be "indefinitely deferred." In addition, donors who have spent five years or more in France, and U.S. military personnel stationed in a number of different Northern European countries, would be ineligible to donate blood (FDA 2001).

- **Testing and quarantining blood** After blood is donated, it is tested for infectious disease. The major diseases of concern are HIV (the virus associated with AIDS), hepatitis B (HBV), and hepatitis C (HCV). Tests have become increasingly sophisticated in an attempt to identify more diseases faster. With many of these diseases, indicators only appear in the blood after a period of time, and newer tests attempt to minimize the time between infection and when the disease can be detected. Lookback procedures have been instituted in cases where infected blood was not caught in time. These procedures involve deferring the infected person from future donations, tracing the donated blood, and contacting patients who received the blood to see whether they have become infected. Many of the changes in Table 6 concern improving and enhancing testing and instituting these procedures.

- **Correcting system deficiencies** The blood industry is expected to follow procedures collectively referred to as Current Good Manufacturing Practice, or cGMP. The FDA has used this type of standard in monitoring and ensuring the safe production of pharmaceuticals, and in recent years it has increasingly held the blood industry to similar standards. The FDA inspects blood centers to ensure that quality controls are in place, and any breaches of safeguards or lapses of standards are fully investigated.

TABLE 6

A time line of regulatory and technological changes in the production of blood and blood products

Pre-1983
- Testing for syphilis and hepatitis B

1983
- AIDS deferral questioning[1]

1984
- Accutane deferral questioning
- New methods for compatibility testing[1]

1985
- HIV screening test (Anti-HIV)[1]

1987
- ALT testing for liver disease (AABB standards required; later dropped)
- Hepatitis B core antigen test (Anti-HBc) implemented by blood centers
- Deferral questioning for human pituitary growth hormone (for CJD)[1]

1988
- Anti-HTLV-1 screening test[1]
- Computerization regulated[1]
- New deferral questioning for HIV-2 risk (for example, travel to Africa)
- Deferral questioning for aspirin for platelet donation[1]

1989
- Additional computerization requirements[1]

1990
- Syphilis and gonorrhea deferral questioning
- Hepatitis C screening test—first generation[1]

1991
- Hepatitis B core antigen testing (Anti-HBc)[1]
- Syphilis deferrals (clarification of FDA policy)
- Error and accident reporting for licensed blood centers[1]

1992
- 2nd generation hepatitis C screening test (Anti-HCV) , Anti-HIV-1 and HIV-2 testing required[1]
- HIV deferral questioning expanded[1]
- Deferral questioning for transfusion within previous 12 months, tattoos, hepatitis, Chagas' disease, babesiosis, accupuncture, and needle sticks[1]

1993
- Deferral questioning for medications (Proscar, Accutane, and Tegison)[1]
- Post-donation information reporting requirements[1]
- History of hepatitis deferral questioning[1]
- Validation of computer systems[1]

1994
- 3rd generation of HCV testing
- Malaria exposure deferral questioning[1]

1995
- CJD deferral questioning
- Deferral of prison inmates[1]
- Quality assurance unit
- Deferral questioning for receipt of dura mater (CJD)[1]

1996
- New generation of HIV testing (p24 antigen)[1]
- Additional requirements for HCV supplemental testing[1] required
- CJD deferral revised[1]
- Additional deferral questioning for HIV group O[1]

1998
- Anti-HTLV-II[1]
- HCV targeted lookback[1]

1999
- Deferral for questioning for Propecia medication[1]
- Nucleic Acid Testing for HCV and HIV (under IND, but near universal use)
- UK vCJD donor referral policy[1]
- HCV lookback expanded[1]
- Deferral questioning for Soriatane medication

2000
- Movement toward universal leukocyte reduction—ARC announces 100% leukoreduced; FDA BPAC recommends 100% leukoreduction.
- Required reporting of biologic product deviations (regulates all blood centers and hospital transfusion services)[1]
- Expanded deferral for exposure to malaria[1]

2001
- Expanded UK vCJD donor deferral policy
- ARC implements October 2001
- DoD implements October 2001
- FDA issues draft guidance for implementation in 2002

Note: AIDS (acquired immunodeficiency syndrome), HIV (human immunodeficiency virus), ALT (alinine aminotransferase), AABB (American Association of Blood Banks), FDA (Food and Drug Administration), CJD (Creutzfeldt-Jakob Disease), vCJD (variant Creutzfeldt-Jakob Disease [Mad Cow Disease]), ARC (American Red Cross), HCV (Hepatitis C virus), IND (Investigational New Drug), UK (United Kingdom), BPAC (Blood Products Advisory Committee), HTLV (human T-cell lymphotropic virus), DoD (Department of Defense).

[1] FDA (Food and Drug Administration) regulation/guidance.

Source: American Association of Blood Banks.

Technological developments will continue to play a central role in assuring blood safety. Three technologies are expected to have important safety and cost impacts in the near future:

- **Nucleic acid amplification testing (NAT)** This gene-based technology has not yet been approved by the FDA, although it is now used to screen most blood for HIV and HCV under an Investigational New Drug (IND) protocol. NAT testing for HBV is under development, and the technology may have applications for other infectious diseases as well. It is estimated to add 8 percent to the current $100 price of a unit of red blood cells and 5 percent to the $49 price of a unit of platelets (Muse and Associates 2000; America's Blood Centers 2001).[9] NAT testing of blood would reduce the likelihood of transfusing an infected unit from about .00015 percent to .00010 percent for HIV and from .001 percent to .00013 percent for HCV.

- **Leukoreduction** Leukocytes (white blood cells) in transfused blood can cause adverse reactions. These may be mild or may involve serious complications for patients with weakened immune responses. Leukoreduction filters out the leukocytes to reduce these risks but the process can also remove red blood cells and platelets. Leukoreduction increases the cost of red blood cells and platelets by about one-third (Muse and Associates 2000). Current proposals to expand the application of this technology from blood transfused to immunocompromised patients to the entire blood supply have caused controversy.

- **Pathogen inactivation** These methods neutralize bacterial and viral agents in blood. Existing methods can only be used with plasma, but new methods are under development for whole blood and platelets. This technology would enhance the safety of the blood supply, but industry sources report that it could very substantially increase the cost of blood.

A strategy for accounting for blood cost increases in the future

The market basket is used by the Congress in setting legislated hospital updates. It also provides a foundation for MedPAC and CMS recommendations for hospital updates and is a reference point for analyzing changes in input prices in the hospital sector. It is important that the market basket be comparable over time (that is, it should measure "the same thing" at different times). However, changes should be made when they improve the measurement of costs and can be implemented with available data.

Changes to the market basket may or may not increase the PPS payment update. Changes in market basket weights and application of new price proxies to modified weights both affect overall market basket growth. The impact depends on the magnitude of weight changes and the relative growth rates of new price proxies.

As described above, through fiscal year 1996 the market basket included a separate cost component for blood and used the PPI for blood and derivatives as price proxy. CMS dropped this component when it revised the hospital market basket for fiscal year 1997, citing the lack of appropriate data for calculating a weight for blood services. Instead, the agency combined blood with the cost component for chemicals, adjusting it by the PPI for industrial chemicals although this index does not closely track changes in the price of blood.

[9] Platelets are a product of cetrifuging whole blood.

RECOMMENDATION

When CMS next revises the hospital market basket, it should explicitly account for the cost of blood and blood products by reintroducing a separate component for their prices.

The BIPA requires that CMS give special attention to the adequacy of payment for blood and blood products when revising the market basket. The agency could reintroduce a separate cost component for blood using the PPI for blood and derivatives as price proxy. CMS dropped the component for blood in the revision of the hospital market basket for the fiscal year 1997 update. The market basket used before fiscal year 1997 included a component for blood services with a weight of 0.6 percent. After the revision, the blood services component was merged with the chemicals component, increasing its weight from 3.100 percent to 3.795 percent in 1997. The chemicals component is adjusted using the PPI for industrial chemicals.

CMS explained that the decision was motivated by the lack of appropriate data for calculating a weight for blood services. However, it could explore the use of alternative data sources to develop a weight including the Medicare cost report, CMS's case file for inpatient services (the MedPAR file), data from independent researchers, and the Department of Commerce data used to construct the weight before 1997. The share of blood-related costs in hospitals has been relatively stable over time and is consistent across studies and data sources. Alternatively, CMS could estimate a weight by using the weight for blood services in the market basket before 1997 and adjusting it for relative changes in its price proxy between fiscal years 1996 and 2001.

The PPI for industrial chemicals that CMS currently uses in the market basket is unrelated to blood, both conceptually and in the underlying data used for measurement. In addition, the trend in this PPI component has not tracked blood prices closely, particularly since 1995. Between 1995 and 1999, the annual change in the PPI for industrial chemicals was -1.9 percent, compared with 6.8 percent for the blood and derivatives PPI (Table 5, page 11). ■

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APPENDIX A

Safety regulation, standards, and technology

This appendix presents detailed information on blood safety regulation and technologies. It begins with a discussion of private standards, government regulation, and legal issues. It then provides an overview of methods to ensure blood safety, distinguishing between organizational approaches and technological approaches. This is followed by detailed discussions of factors affecting blood supply, costs, and safety now and potentially affecting price in the future.

Standards and regulation

Safety practices of blood collection and processing centers are affected by standards set by private organizations, regulations issued by federal agencies, and tort law related to transfusion safety. All have affected blood banking practices since 1984 and can be anticipated to affect practices over the next 10 years.

Private sector standards

The leading private voluntary standards-setting organization in blood banking and transfusion medicine is the American Association of Blood Banks (AABB). It establishes standards for blood bank blood component collection, processing, and transfusion and publishes them in its *Standards for Blood Banks and Transfusion Services*. These standards, as well as those in the AABB Accreditation Information Manual, form the basis of the association's accreditation and assessment program for blood banks and transfusion services.

AABB committees develop and revise standards, with input from other private organizations (e.g., the College of American Pathologists) and from federal organizations (e.g, the Food and Drug Administration [FDA], Armed Services Blood Program Office). AABB publishes guidance documents providing further information supplementing requirements in standards with information on implementation.

Since 1957, AABB has published twenty editions of its *Standards for Blood Banks and Transfusion Services*. The twentieth edition was effective January 2001. AABB revises the standards on an 18 month cycle. The standards cover all aspects of blood collection, testing, processing, storage, distribution, and transfusion.

AABB conducts proficiency testing programs with the College of American Pathologists for the testing of donor blood for viral markers of infectious disease.

The AABB accreditation program grants accreditation for specific activities. Each facility's assessment reflects the activities it performs. Activities of donor centers include collection, processing, testing, and distribution. Activities of transfusion services include compatibility testing, pretransfusion testing, and blood administration.

Government regulation

The blood and blood products industry is subject to regulation by federal agencies, principally the FDA. The FDA may regulate any aspect of the industry except medical practice standards. The agency issues formal regulations and, since the mid-1980s, has frequently issued guidance documents stating agency policy on specific issues. These documents indicate the FDA's views of how to fulfill regulatory requirements, and although they do not have the legal force of regulations and are not enforceable as regulations, they carry weight in court. The blood industry believes it is compelled to follow these guidances. Although not required by law, the FDA identifies guidances that are significant interpretations of statute or regulation. Unless a guidance addresses an urgent public health issue, the FDA allows a comment period before it is effective (Epstein and Gustafson 2001).

All facilities preparing or testing blood or blood components for transfusion must register with the FDA. Blood and blood products are licensed as biologics, and establishments producing them must be licensed. Since 1998, a single biologics license covering both the facility and all of its products has been issued by the FDA. Almost all American Red Cross and independent blood centers are licensed because they supply blood across state lines. Most hospital-based blood centers do not require licenses. A manufacturer of a licensed product must annually update its registration, comply with good manufacturing practices, and meet certain reporting requirements. The FDA inspects all blood centers—licensed and unlicensed—at least every two years. If an inspection uncovers a violation threatening blood safety, the FDA can authorize suspension or revocation of a license for a specific product or for the blood center, seizure of a product, court injunction, or criminal prosecution.

The FDA requires licensed blood centers, unlicensed but registered blood centers, and transfusion services to report errors or accidents (now called biological product deviations) that affect blood and blood components that have been distributed (FDA 2000). Both licensed and unlicensed blood centers must comply with FDA regulations on donor deferral, deferral registries, blood testing, blood quarantining, and correction of system deficiencies.

The blood products industry is regulated by other federal agencies, including CMS, the Occupational Safety and Health Administration, the Department of Transportation, and the Centers for Disease Control and Prevention. Blood centers and hospitals are also regulated by individual states. FDA regulation is the most important federal regulatory activity pertaining to blood safety.

Legal action

Civil action under tort law provides a recourse for patients harmed by unsafe products. In the case of blood, patients who have contracted hepatitis or AIDS have brought suit against blood banks and health care providers for damages resulting from contaminated blood. The prospect of serious financial consequences resulting from such legal action may provide an incentive for blood banks to ensure the safety of blood products.

Existing state law and court precedents have limited the prospects of damages for transfusion-transmitted disease. The provision of blood has been viewed under law as a medical service, rather than a sale of a product. This prevents application of rules of strict liability to blood banks, making it more difficult for plaintiffs to win damages. Many states have enacted statutes—so-called blood shield laws—declaring provision of blood a service and not a sale.

A patient suing for damages must generally show that a blood bank did not comply with the standard of care. Typically, if the blood bank complied with FDA regulations, AABB standards, or American Red Cross practices it was considered to have met the standard of care. However, in the 1990s some courts questioned whether industry standards were adequate (Labensky and Coomer 1998). Although there has not been an authoritative ruling yet, some courts have held that blood centers have a duty to adopt certain blood safety measures beyond those required by the FDA and national standards. At a minimum, strong incentives exist for blood banks to comply with FDA regulations, AABB standards, and Red Cross practices. If more courts abandon the traditional standard of care, the prospect of litigation may lead blood banks to implement more blood safety measures.

Methods to ensure safety of blood products

Blood collection centers, blood product manufacturers, and hospital transfusion services take multiple steps to maintain the safety of blood and blood products. They can be classified as organizational and technological approaches to reducing the risk of diseases transmission and transfusion-related errors.

Organizational approaches to blood safety

The initial steps in reducing the risk of transfusion-associated infection involve selection and screening of potential blood donors. Donor screening is particularly important for infectious agents where no routine lab tests exist to identify contaminated units. Screening can identify infectious donors between infection and creation of antibodies that allow test identification of an infection. However, it can exclude many uninfected blood donations, contributing to blood shortages and resulting in health risks to the population.

In addition to screening individual donors, blood banks and regulators exclude certain classes of potential donors from giving blood for specified periods or indefinitely. Donor deferrals can be based on risk factors for infectious diseases including medical history and travel to specified regions. Deferral of a class reduces the pool of potential donors, reducing the supply of donated blood.

Additional organizational tools are used to insure transfusion safety after blood donation. Blood centers and manufacturers of blood products must comply with professional quality standards to prevent manufacturing errors. Each year mistransfusion results in more fatalities than transfusion-related HIV transmissions (AuBuchon 2001). Blood centers clearly label blood to prevent transfusion of the wrong blood into patients. Hospital operating procedures must be designed to prevent transfusing the wrong blood into a patient. If a blood center determines that potentially tainted blood has been used in transfusions, recipients are notified and informed of the risk of infection. Blood centers may run such lookback programs involving identification of and contact with large groups of recipients, often long after the event.

Technological approaches to blood safety

The blood banking industry and regulators also use technological methods to prevent transfusion-associated infection. These involve identification of blood carrying infectious disease, inactivation of disease-causing agents, and modifications in the processing of blood products.

Testing

Blood testing techniques can identify major infectious agents, determine blood type and Rh status, and otherwise test for compatibility. Blood centers test all blood for syphilis, HIV, hepatitis B, hepatitis C, and human T-lymphotropic virus (HTLV). Some centers may also test for sickle cell anemia and cytomegalovirus.

Blood testing technology has advanced greatly since 1984, increasing the number of screening tests from two to nine. When new tests are introduced, old ones generally are not dropped. The FDA currently requires that blood centers perform two tests each for HIV and hepatitis B. A new gene-based testing technology, nucleic acid amplification testing (NAT), has not yet been approved by the FDA but is now used to screen most blood in the nation for HIV and hepatitis C. Although the FDA hopes that a NAT test will replace one of the current tests for HIV, it may be used as a supplemental test rather than as a replacement (Epstein and Gustafson 2001).

Processing

After whole blood is collected, it is subject to several processing steps before it is used in transfusion. Plasma is fractionated to derive a wide variety of blood derivatives such as albumin, immune globulins, and coagulation factors. Several steps in processing are designed to reduce risks of adverse reactions or transmission of infection.

- **Irradiation** Transfusion-associated graft versus host disease (TA-GVHD) may result from receipt of blood components that contain viable T lymphocytes. The condition occurs when lymphocytes from the donor recognize antigens in the recipient as foreign, triggering an immune response. TA-GVHD is unresponsive to immunosuppresive therapies. Death typically occurs within three to four weeks after transfusion, with mortality rates of about 90 percent. Patients with hematologic and certain other cancers are at risk, as well as those with deficient immune systems. Gamma irradiation of cellular blood components to be given to at-risk patients prevents proliferation of T lymphocytes. Irradiation of blood products for other patients is not recommended due to the very low risk of TA-GVHD.

- **Viral inactivation** Viral infectious agents in blood can be neutralized by viral inactivation techniques, which can eliminate agents that cannot be identified by current tests. Viral inactivation also can eliminate new viruses not yet identified, eliminating the lengthy process of test development and commercialization. Existing techniques, generally involving heating the product or adding solvent and detergent, can be used with plasma but not with whole blood or its cellular components. New techniques applicable to platelets are in clinical trials, while others applicable to red blood cells are under development.

- **Leukoreduction** Leukocytes (white blood cells) present in transfused whole blood and cellular blood components can cause adverse reactions. Reactions can range from a fever and chills to more serious reactions such as pneumonia for immunocompromised patients. Leukoreduction can reduce these risks by filtering white blood cells from blood product. It can be done at the blood center (prestorage leukocyte reduction), at the hospital (in-lab post-storage leukocyte reduction), or at the patient's bedside. Possible disadvantages include cost and potential for a loss of red blood cells and platelets.

New factors affecting blood supply, costs, and safety

Three issues are currently at the center of the discussion of blood safety, supply, and price: NAT, universal leukoreduction, and donor deferrals related to Variant Creutzfeldt-Jakob Disease (vCJD, or bovine spongiform encephalopathy, the human form of "mad cow" disease).

Nucleic acid amplification testing

One of the key concerns in blood testing is the time after the donor first becomes infected and before antibodies or antigens can be detected. NAT testing can detect genetic material of a variety of diseases, including HIV and hepatitis C. In the case of HIV, the time between infection and possible detection is potentially reduced from 16 days to 10 days (Redhead 2000).

This reduction has a clear scientific advantage. However, unlike in the mid-1980s, the likelihood of receiving HIV-infected blood is already quite low. Before NAT testing, the rate of HIV infection in the blood supply was 1 in 677,000 units (Valinsky 2001). The introduction of NAT could reduce this to 1 in 1,000,000 units and increase the detection of HIV infected blood by about 12 units per year nationwide (Redhead 2000). A study commissioned by AABB estimated that NAT testing adds about $8.00 to $8.50 to the $100 price of a unit of blood in 2000 (Muse and Associates 2000). In the case of HIV, an 8 percent increase in price would be associated with a 33 percent decrease in the likelihood of an HIV- infected unit of blood being transfused from about 0.00015 percent to 0.00010 percent.[1]

The cost effectiveness of NAT testing is stronger in the case of HCV. The time between infection and possible detection for HCV could be reduced from 70-80 days to 10-30 days. This should reduce the rate of HCV infected blood from 1 in 100,000 units to between 1 in 500,000 and 1 in 1,000,000 units (Valinsky 2001). NAT testing could detect an additional 214 units of HCV-infected blood per year. In this case, the 8 percent increase in price would be associated with an 87 percent reduction in the likelihood of an HCV infected unit of blood being transfused from about 0.001 percent to 0.00013 percent (assuming a post-NAT testing rate of infected units of 1 in 750,000).[2]

The study commissioned by the AABB estimated the increase in costs in 2000 for both red blood cells and platelets for NAT testing associated with Medicare inpatient care. The cost for NAT testing of platelets is less per unit, with costs ranging from $2.15 to $2.64 per unit. Data from the National Blood Data Resource Center's 1998 survey indicate that approximately 24.7 million units were transfused annually in U.S. hospitals. About half of these units, 12.3 million, went to Medicare patients, with 90 percent of them (11.1 million) used in the inpatient hospital setting (Muse and Associates 2000). Given these figures, NAT testing increased hospital costs by an estimated $47.2 million annually for Medicare inpatient care.[3]

[1] Calculations based on AABB and Congressional Research Service data.

[1] Calculations based on AABB and Congressional Research Service data.

[3] Calculations based on AABB data on NAT cost of whole blood and platelets referenced previously.

The FDA has not yet formally approved NAT testing. However, given its potential to improve blood safety, the FDA has allowed the blood industry to use NAT testing since 1999 under the Investigational New Drug (IND) application process. Blood banks now test almost all blood for HIV and HCV using NAT technology (Wiegmann 2001). The lack of FDA approval complicates matters. Without FDA approval, commercial insurers will not reimburse for costs associated with NAT testing.

Universal leukoreduction

People receiving transfusions need red blood cells or other blood components and may actually be harmed by leukocytes (white blood cells), as discussed earlier. Some patients with weakened immune responses, such as infants, cancer patients, and AIDS patients, or those who require repeated transfusions, are especially at risk. These groups are already given leukoreduced blood.

Controversy arises with proposals to leukoreduce the entire blood supply. Opponents of universal leukoreduction suggest that the process be limited to patients who may be at risk of adverse transfusion reactions. They highlight the significant additional costs of leukoreduction and the possible loss of 10 percent of red cells associated with the filtering process. Proponents of universal leukoreduction point out the enhanced safety of leukoreduced blood and the value of avoiding adverse transfusion reactions. The American Red Cross is in the process of converting to 100 percent leukoreduced units. The FDA's Blood Products Advisory Committee has also recommended universal leukoreduction, as has the HHS Advisory Committee on Blood Safety and Availability.

A survey and study conducted for the AABB found leukoreduction increased the cost of a unit of red blood cells in 2000 from $99 per unit to $132 per unit. Analysts with America's Blood Centers estimate an increase in price in 2000 from $90 per unit to $125 per unit and surveys by America's Blood Centers found that leukoreduction was less expensive for platelets, increasing price in 2000 from $49 to $66 per unit. This is consistent with the AABB study finding that leukoreduction added $16.55 to the cost of a unit of platelet concentrates (Muse and Associates 2000).

The AABB study went on to estimate the cost increase associated with Medicare inpatient beneficiaries for both red blood cells and platelets. It found that complete leukoreduction would increase costs to Medicare by approximately $200 million annually. This would increase inpatient blood costs of Medicare beneficiaries in 2000 from $755 million to $955 million.[4] Not all of the $200 million would represent new spending by moving to universal leukoreduction because most of the blood supply is already leukoreduced.

The HHS Advisory Committee on Blood Safety and Availability has recommended that the Secretary of HHS "assure adequate funding for this effort," although it did not specify a particular solution. The Advisory Committee recommended that the Secretary appoint a representative of CMS as a non-voting member of the Advisory Committee (Nightingale 2001).

[4] Calculated from Muse and Associates cost estimates for leukoreduction and America's Blood Centers' average service fees in 2000 for red blood cells, platelet concentrates, and platelets pheresis (America's Blood Centers, 2001).

Donor deferrals related to Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease

Deferral of a class of donors may reduce risk of disease transmission but significantly reduce the pool of potential donors. This is currently occurring with regard to vCJD. The FDA has suggested that potential donors who have lived for specified periods in the United Kingdom or France, as well as U.S. military personnel stationed in a number of different northern European countries, be ineligible to donate blood; these deferrals will reduce the blood supply by about 5 percent (FDA 2001). Such a reduction in the blood supply can have serious implications in terms of both cost and possible shortages. In 1999, 13.9 million units of blood were donated and hospitals transfused 12.4 million units. Not all blood donated can be used, with about 2 percent discarded, so a 5 percent reduction would leave 12.9 million units: still more than hospitals transfused, but a much tighter supply (National Blood Data Resource Center 2001). Neither the FDA staff who estimated the 5 percent decline nor the blood industry has estimates of the cost and possible price implications of replacing these donors (Williams and Panarites 2001).

Future issues that may affect the price of blood and blood products

A number of current issues will be of continuing concern in the future. In addition, there are new issues and developments that may affect the safety, supply, and cost of blood and blood products.

Nucleic acid amplification testing

NAT testing has the potential to go beyond its current ability to improve the identification of HIV and HCV infected blood. NAT testing for HBV is in development, and the testing may have applications for other infectious diseases.

Donor recruitment

In the face of increased donor deferrals, the blood industry is looking for additional means to encourage donor participation. Almost all of these methods, from increased public outreach campaigns to computer-assisted donor screening, will add to the cost of a unit of blood.

Pathogen inactivation

Research in progress would allow the blood industry to inactivate viruses as well as bacteria in red blood cells and platelets. At least one approach for inactivating viruses and bacteria in platelets has reached Phase III clinical trials, and a method for red blood cells is progressing along the same track. This new technology would enhance the safety of the blood supply, but the AABB reports that pathogen inactivation could lead to very substantial increases in the cost of blood products.

Testing for additional infectious diseases

A number of other infectious diseases that may be detectable in blood at donation in the near future; some, such as vCJD, are now being screened using deferral techniques. They include:

- Hepatitis A virus
- vCJD
- Chagas' Disease, associated with chronic infections by a parasite endemic to Mexico, Central America and South America.
- Babesiosis (Texas fever), which is caused by a red cell parasite, usually transmitted by the bite of an infected deer tick. ■

APPENDIX B

Commissioners' voting on recommendation

Commissioners' voting on recommendation

In the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), the Congress required MedPAC to call for individual Commissioner votes on each recommendation, and to document the voting record in its report. The information below satisfies that mandate.

Recommendation

When CMS next revises the hospital market basket, it should explicitly account for the cost of blood and blood products by reintroducing a separate component for their prices.

Yes: *Braun, DeBusk, Feezor, Hackbarth, Loop, Muller, Nelson, Newhouse, Newport, Raphael, Reischauer, Rosenblatt, Rowe, Stowers*
Absent: *Burke, Smith, Wakefield*

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